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# RISK TUNNEL

#### **Adverse Events**

(No need to have a causal relationship)

## **Key Drivers**

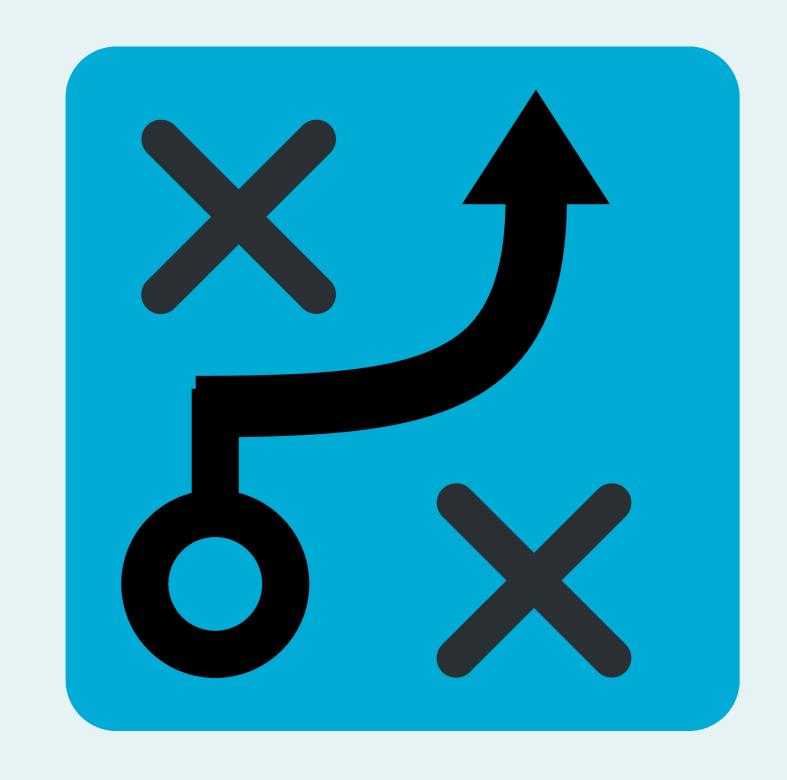
**Adverse Drug Reaction** 

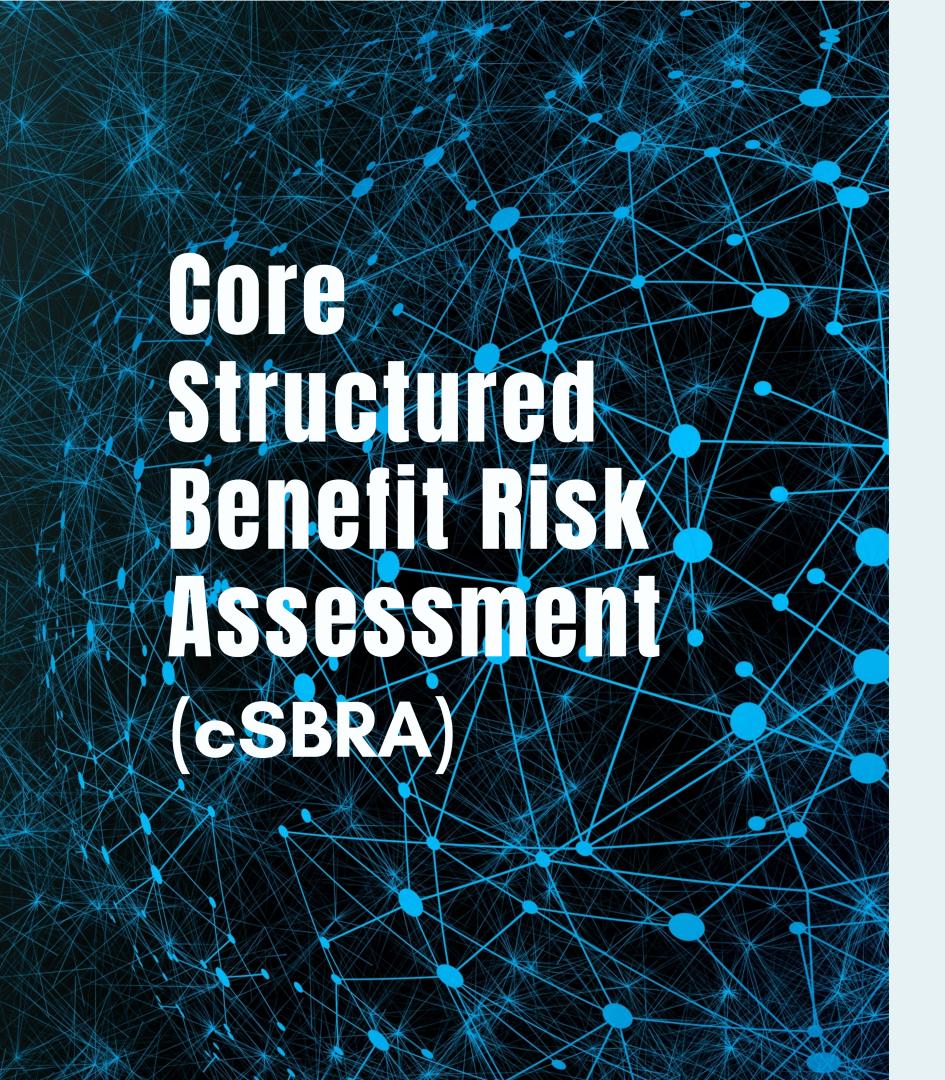
(Causal relationship is suspected or established)

#### **Safety Specifications**

Important Potential Risk
Important Identified Risk
Missing Information

# Core Structured Benefit Risk Assessment (cSBRA)





- A living document/continous process which involves weighing the benefit vs the risk of a product for a particular indication
- Core meaning its an internal document (not submitted to the agency but serves as source document for many regulatory documents)
- Prepared at end of phase 2 (EOP2)
- Involves crossfunctional collaboration

# Figure 1: FDA's Benefit-Risk Framework

# Benefit-Risk Integrated Assessment

## Benefit-Risk Dimensions

Dimension	Evidence & Uncertainties	Conclusions & Reasons
Analysis of Condition		
Current Treatment Options		
Benefit		
Risk & Risk Management		

## Opportunities for Structured Benefit/Risk **Assessment during Drug Development**

### **Assess patient** group views on:

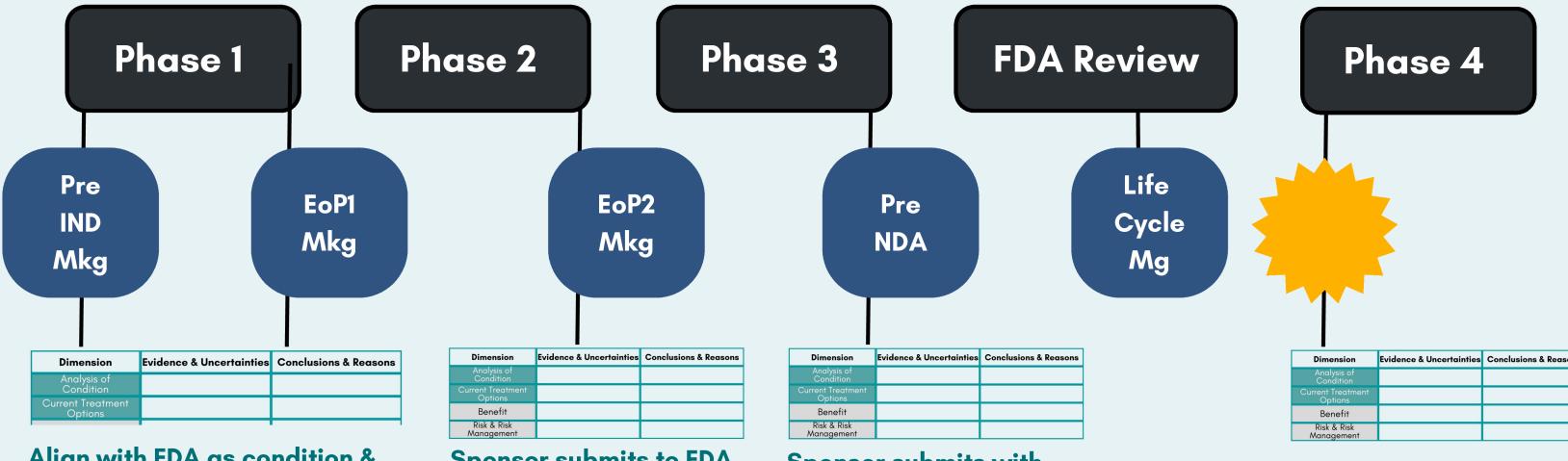
- 1. Analysis of Condition
- Treatment Option

Share clinical data confidentiality with patient group and seek feedback on:

- Benefit
- Risk
- Risk Management

Provide advisory committee members

with in briefing document to frame the meeting

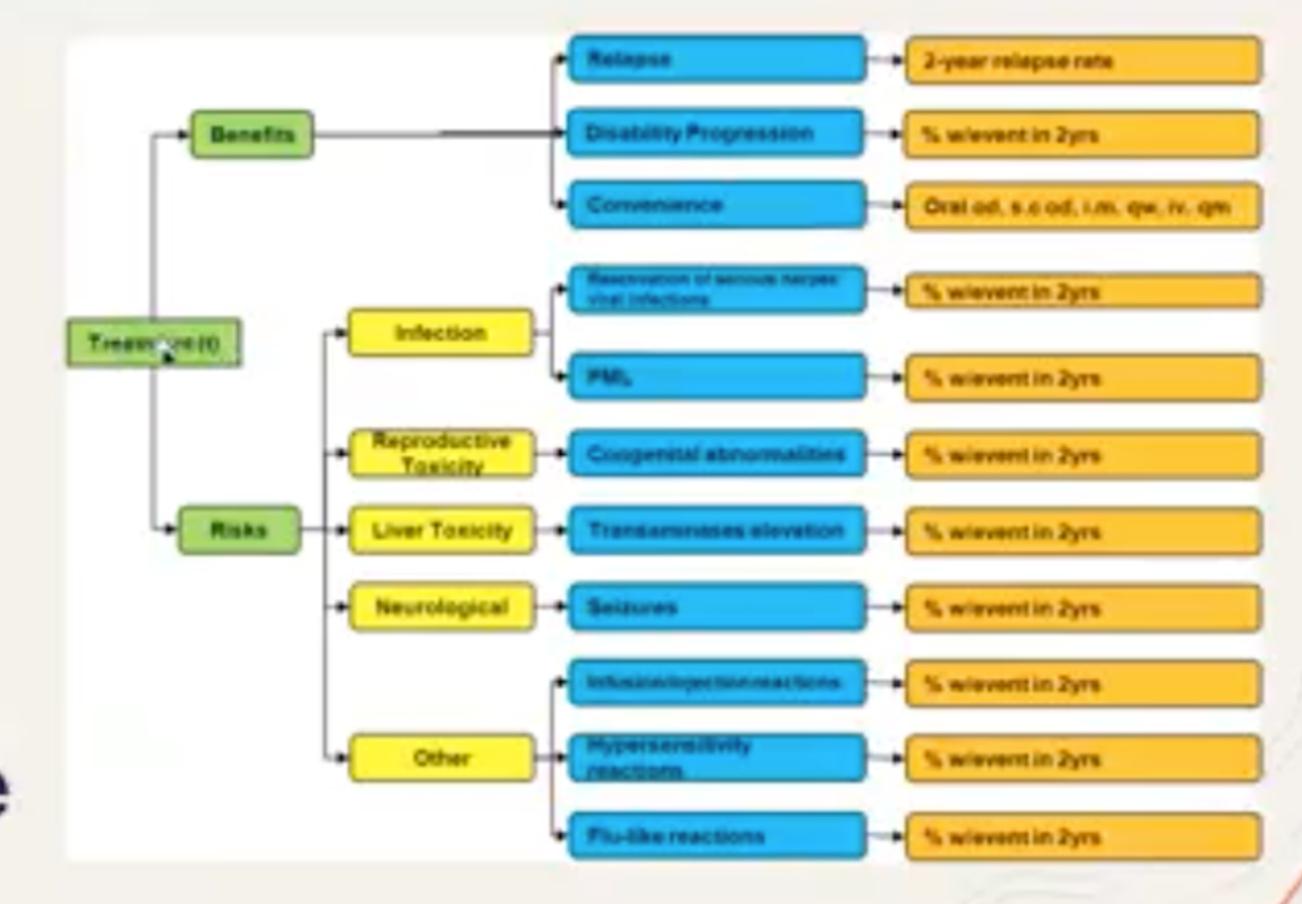


Align with FDA as condition & treatment option

Sponsor submits to FDA

Sponsor submits with **NDABLA** 

**FDA Post Final** 



# Value Tree